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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,003	03/10/2004	Roman Kotitz	SCH-1704-D1	4256

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,003	KOTITZ ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20,22,23 and 30-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,20,22,23 and 30-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry & Claim Status

The preliminary amendment filed on November 29, 2004 has been acknowledged and entered.

Claims 19, 20, 22, 23, 30-41 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34 and 38 are indefinite because "the media" lacks antecedent basis. Furthermore, claims 34 and 38 are vague in stating the relationship between the compound and the viscosity of the media or the media.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 19, 20, 22, 23, 30-33, 34-37, 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Colin et al. (US 5,773,307).

Colin teaches a particle containing a metal core to which at least one anti-ligand is fixed directly or indirectly. The metal core of the particle is chosen from materials which are intrinsically magnetic (ferromagnetic) or magnetizable (paramagnetic), such as complex salts of the oxides, borides, sulfides of iron, cobalt, nickel and the rare-earth elements. Ferromagnetic/ferrimagnetic particles possess permanent magnetism. Since the magnetic particles of Colin are made of the same materials as those of the present invention and possess intrinsically magnetism, the particles of Colin are inherently ferromagnetic/ferrimagnetic. The metal core is chosen so that it is free of residual magnetism, and its mean size is between 3 and 30 nm. The particles may comprise an envelope in addition to the metal core. The composition of the envelope is chosen so

that it allows the attachment of ligand and of anti-ligands. The envelope may be a natural polymer or chemically modified polymer such as polysaccharide such as agarose, dextran, cellulose derivatives such as carboxymethylcellulose; a protein such as gelatin and a polymer of albumin; a synthetic polymer, chemically modified or otherwise such as acrylic or methacrylic acids. The mean size of the general reagent particle is between 20 and 100 nm. (see col. 3, lines 33-56). The analyte to be identified can be a ligand comprising an anti-ligand specific recognition site. (see col. 3, lines 3-5). Ligand and anti-ligand refer to any biological molecules capable of forming a ligand/anti-ligand complex such as the complexes antigen/antibody, antibody/hapten, hormone/receptor; protein/antibody, biotin/streptavidin; lectin/sugar; chelator/chelated molecule; oligonucleotide/oligonucleotide hybrid; etc. (see col. 1, line 64-col. 2, line 6). Since the magnetic particle of Colin is made up of the same materials as that of the present invention, it also has a relaxation time in aqueous media of 10^{-8} to 10^{-1} seconds and the moments of the ferromagnetic/ferrimagnetic substances in Colin is uniform or substantially uniform; and the Brownian relaxation of the particle proceeds faster than its Neelian relaxation under measuring conditions for detection of analyte or binding reaction by its double refraction behavior or relaxation behavior of double refraction in the composition.

Claims 19, 20, 22, 23, 30-33, 35-37, 39-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Klieber et al. (US 6,255,477).

Klieber teaches magnetic glass particles containing a magnetic core coated with a glass layer having a substantially pore-free glass surface. The particles are used for

separating biological materials such as nucleic acids. The particles have an average particle size of less than 100 microns. The magnetic core may be a composite material containing a mica core and ferromagnetic magnetite particles immobilized on the mica core, and the glass layer contains boron oxide. Magnetic core materials include magnetite (Fe3O4) and (Fe2O3) (iron oxides). In operation, the magnetic particles are brought to contact with the sample containing a biological material to be detected or separated. Biological materials are cells, viruses, bacteria, haptens, antigens, antibodies and nucleic acids. The glass surface may also be coated with a layer of a protein such as a streptavidin (binder). (see col. 4, line 42-col. 5, line 48; col. 6, lines 4-29). Since the magnetic particle of Klieber is made up of the same materials as that of the present invention, it also has a relaxation time in aqueous media of 10^{-8} to 10^{-1} seconds and the moments of the ferromagnetic/ferrimagnetic substances in Klieber is uniform or substantially uniform; and the Brownian relaxation of the particle proceeds faster than its Neelian relaxation under measuring conditions for detection of analyte or binding reaction by its double refraction behavior or relaxation behavior of double refraction in the composition.

Claims 19, 20, 22, 23, 30-33, 35-37, 39-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Weitschies et al. (US 6,027,946).

Weitschies teaches the use of colloidal ferromagnetic or ferrimagnetic substances also referred to as magnetic labeling and the relaxation of their magnetization is determined as a measurement variable. The magnetic labeling is combined with substances that are to be identified- analytes- or structure specific

substances. The sizes of the particles range from 1 nm to 1000 nm. The Brownian relaxation of the ferromagnetic particles proceeds faster than Neelian relaxation under measurement conditions in the unbound state. Structure specific substances are defined as all substances that bind specifically to certain structures. Structure-specific substances are antibodies, biotin, receptors, proteins, peptides, enzymes, enzyme substrates, nucleic acids. (see col. 5, lines 26-40). Ferromagnetic/ferrimagnetic colloidal particles can be produced with a stabilizing shell made of the structure-specific substance or the analyte that is to be identified by the particles being put after production directly into a solution of the structure specific substance, optionally in the presence of other adjuvants, such as proteins, carbohydrates, as well as natural, synthetic or partially synthetic surface-active substances. (see col. 5, line 61-col. 5). The ferromagnetic/ferrimagnetic colloidal particles made of iron, iron oxides, barium ferrites, strontium ferrites, cobalt, nickel, and chromium dioxide, whose Neelian relaxation time is longer than the Brownian relaxation time. (see col. 7, lines 19-23). Regarding the limitations that the ferromagnetic/ferrimagnetic substance's relaxation time in aqueous media; and the moments of the particles is uniform or substantially uniform, since the components or make-up of the colloidal ferromagnetic/ferrimagnetic particles of Weitschies are the same as that of the present invention, the ferromagnetic/ferrimagnetic particles of Weitschies must inherently have the same characteristics or relaxation time in aqueous media as such claimed in the present invention as well as the moments of these ferromagnetic/ferrimagnetic substances must have the uniform or substantially uniform.

Claims 19, 20, 22, 23, 30-33, 35-37, 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman et al.(US 5,076,950).

Ullman teaches a method of using magnetic particles to separate a substance from a liquid medium, wherein the magnetic particles comprises of ferromagnetic particles immobilized with a complementary specific binding member (structure specific substance) for binding to the target analyte. The magnetic particles are bound to the target analytes via complementary binding member. This combination reads on the limitation of claims 20, 33, 37. The ferromagnetic particles range in size from 5 nm to 1 micron, preferably about 1nm to 250 nm. (see col. 10, lines 14-26) and can be intrinsically magnetic and are nickel, cobalt, oxides, borides, sulfides of iron. (see col. 10, lines 27-34). The magnetic particles contain a core and surface functional groups or coated with a protein such as albumin, avidin, immunoglobulin or a carbohydrate such as a dextran, chitosan or amylose. (see col. 10, lines 35-49). Coating the magnetic particles with a macromolecule, such as a high molecular weight polymer, can increase their colloidal stability. (see col. 11, lines 1-65). The target analyte or the structure specific substance can be a protein such as an antibody, antigen, biotin, avidin or streptavidin, receptors. (see col. 4, line 41-col. 5, line 15). Since the magnetic particle of Ullman is made up of the same materials as that of the present invention, it thus must have a relaxation time in aqueous media of 10^{-8} to 10^{-1} seconds and the moments of the ferromagnetic/ferrimagnetic substances in Ullman is uniform or substantially uniform; and the Brownian relaxation of the particle proceeds faster than its Neelian

relaxation under measuring conditions for detection of analyte or binding reaction by its double refraction behavior or relaxation behavior of double refraction in the composition.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
December 21, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/26/04